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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,964	11/08/2000	Philip A. Beachy	JHUC-P04-010	3944

28120 7590 10/29/2003

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BOSTON, MA 02110-2624

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/29/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/708,964

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 15-17, 20, 22, 23, 27, 28 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 15-17, 20, 22, 23, 27, 28 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **First Office Action on the Merits**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 12, 2003 has been entered.

### ***Status of the Application***

2. Claims 1, 15-17, 20, 22, 23, 27, 28 and 36-40 are pending in the present application. Claim 40 stands withdrawn from further consideration as being drawn to a nonelected invention. Claims 1, 15-17, 20, 22, 23, 27, 28 and 36-39 will be examined to the extent they read on the elected species.

### ***Double Patenting***

3. The provisional rejection of claims 1, 15-17, 20, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/708,974 is withdrawn.

**4. The provisional rejection of claim 21 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/708,974 is made moot by the cancellation of the instant claim.**

**5. The rejection of claims 1, 15-17, 20, 22, 23, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970 is maintained and claims 37-39 are rejected under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970.**

The examiner notes that the terminal disclaimer referred to by Applicant is not of record in the present application.

**6. The rejection of claim 21 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970 is made moot by the cancellation of the instant claim.**

**7. The rejection of claims 1, 15-17, 20, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,288,048 is withdrawn.**

***Claim Rejections - 35 USC § 112***

**8. The rejection of claims 1, 15-17, 20, 22, 23, 27, 28 and 36 under 35 USC 112, first paragraph, scope of enablement, is maintained and claim 37 is rejected under 35 USC 112, first paragraph, scope of enablement.**

Applicant argues that the threshold for undue experimentation has not been met for the instantly claimed invention. Applicant's argument was considered but not persuasive for the following reasons.

35 USC 112, first paragraph, requires that "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such **full, clear, concise, and exact terms** as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention".

The issue is not whether the experimentation is routine or not but whether the present specification provides sufficient guidance to enable the skilled artisan to practice the claimed invention commensurate in scope with the instant claims without undue experimentation. The present specification does not describe the claimed invention in full, clear, concise and exact terms to enable the skilled artisan to make and use the same commensurate in scope with the instant claims.

In order to practice the claimed invention commensurate in scope with the instant claims, the ordinary artisan would have to first determine what applicant's molecule is before he can practice the claimed invention. The present specification lacks a link

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between the claimed invention and the molecules encompassed by the instant claims necessary to practice the present invention. What the present specification provides is a description of what the molecule does, i.e., interacts with smoothened and lessens the severity of a hedgehog gain-of-function, patched loss-of-function, or smoothened gain-of-function phenotype. However, description of what the claimed molecule does rather than what the molecule actually is does not suffice under 35 USC 112.

In summary, what is require is identification of the claimed molecule, apart from those disclosed by the present specification, by the skilled artisan before he can practice the claimed invention. Said identification process results in undue experimentation.

For this reason and those given in previous Office Actions, the rejection of claims 1, 15-17, 20, 22, 23, 27, 28 and 36 under 35 USC 112, first paragraph, scope of enablement, is maintained and claim 37 is rejected under 35 USC 112, first paragraph, scope of enablement.

**9. The rejection of claim 21 under 35 USC 112, first paragraph, scope of enablement, is made moot by the cancellation of the instant claim.**

**10. The rejection of claims 1, 15-17, 20, 22, 23, 27 and 36 under 35 USC 112, second paragraph is withdrawn.**

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11. The rejection of claim 28 under 35 USC 112, second paragraph is maintained and claim 37 is rejected under 35 USC 112, second paragraph.

Applicant argues that the term “prodrug” is defined in the present specification and the claims clearly indicate what types of compounds would fall within the scope of the present claims. Applicant’s argument was considered but not persuasive for the following reason.

The definition of “prodrug” is well known in the art. However, neither the present specification nor the instant claims clearly indicate what types of compounds are considered “prodrugs” by the instant invention. The definition of the term does not indicate what the actual compound(s) are. The skilled artisan would not know what compounds are intended by said term and, thus, he would be unable to determine the metes and bound of the claimed invention.

For this reason and those given in previous Office Actions, the rejection of claim 28 under 35 USC 112, second paragraph is maintained and claim 37 is rejected under 35 USC 112, second paragraph.

**12. The rejection of claim 21 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claim.**

***Claim R jections - 35 USC § 102***

**13. The rejection of claims 1, 20 and 36 under 35 USC 102(b) over Gerashchenko et al. is maintained and claims 38 and 39 are rejected under 35 USC 102(b) over Gerashchenko et al.**

Applicant argues the reference does not teach or suggest the use of a hedgehog antagonist for inhibiting unwanted cell proliferation. According to applicant, the reference only teaches topical administration of jervine and its derivatives as antiinflammatory agents. Applicant's argument was considered but not persuasive for the following reason.

Gerashchenko teaches a decrease in the proliferation of the granulomas formed utilizing jervine (see page 3, paragraphs 2-6). Thus, the reference teaches the inhibition of unwanted cell proliferation using jervine and its derivatives as recited by the instant claims.

For this reason and those given in previous Office Actions, the rejection of claims 1, 20 and 36 under 35 USC 102(b) over Gerashchenko et al. is maintained and claims 38 and 39 are rejected under 35 USC 102(b) over Gerashchenko et al.

***Claim Rejections - 35 USC § 103***

**14. The rejection of claims 15-17 under 35 USC 103(a) over Gerashchenko et al. is maintained and claims 22, 23, 27, 28 and 37 are rejected under 35 USC 103(a) over Gerashchenko et al.**



Applicant's argument and the examiner's response are as discussed above in #13.

For the reason given above in #13 and those given in previous Office Actions, the rejection of claims 15-17 under 35 USC 103(a) over Gerashchenko et al. is maintained and claims 22, 23, 27, 28 and 37 are rejected under 35 USC 103(a) over Gerashchenko et al.

#### ***Other Matters***

15. The examiner notes the double recitation of the term "unwanted" in claims 1, 27 and 28.

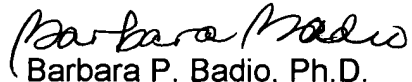
#### ***Telephone Inquiry***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
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BB  
October 28, 2003